UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	**Judge Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

INTRODUCTION

The Medicaid drug overpayment damages and penalties sought by California in this case were the direct result of the "corruption of the [Medi-Cal] reimbursement system caused by Defendants' price reporting practices," not the "result of knowing and deliberate policy decisions made by California." (*Cf.* Defendants' Joint Brief in Opposition to Plaintiffs' Motion for Summary Partial Judgment (docket no. 6801) ("Defs. Opp.") at 3.)

Defendants' Preliminary Statement (Defs. Opp. at 1-3) ignores the critical fact that, at all relevant times, Medi-Cal's pharmaceutical reimbursement methodology and rates were defined and governed by statute and/or regulation. Defendants cannot justify their failure to follow the law based on alleged "understandings" held by Medi-Cal personnel, or comments made by agency personnel, that were not set forth in a formal opinion or ruling. The "facts" on which Defendants selectively rely regarding the alleged "deliberate policy decisions made by California" do not constitute admissible, much less material, evidence as to the meaning of the laws and regulations which governed Medi-Cal's pharmaceutical reimbursement system. Hence, even assuming, solely for the sake of argument, that the recent declarations of Dr. Gorospe were contradictory, that would not create a material issue of fact. Dr. Gorospe is not a member of the California Legislature, which has set Medi-Cal pharmacy reimbursement rates since the mid-1990s; nor did he have any involvement in the 1989 revisions to CAL. CODE REGS. tit. 22, § 51513, which set the basic reimbursement standards that governed for most of the relevant period (i.e.,1994-2004).[1] The import of those statutory and regulatory provisions—and in

[1] Defendants cannot rebut the reality that, at all relevant times, Medi-Cal's reimbursement rate was governed by the 1989 regulation and/or statutes that subsequently modified and eventually supplanted such regulation. Further, as Dr. Gorospe explained at his deposition, although he is the Chief of the Med-Cal Pharmacy Policy Unit, he is several levels below the senior Medi-Cal executives who set policy for the Agency.

particular, the meaning of the term "AWP" as used therein—is a question of law, as to which Dr. Gorospe's understanding is not material.

Further, Defendants' arguments regarding the purported inconsistencies in Dr. Gorospe's declarations are based on an erroneous assumption that Medi-Cal must have intended the enormous spreads that Defendants deliberately created for the drugs at issue. That argument is flawed in at least two respects. First, the economic reality referenced in Dr. Gorospe's February 2009 Declaration (i.e., that Medi-Cal currently reimburses providers for pharmaceutical products at some amount above providers' actual acquisition costs) does not mean that the system was intentionally designed to allow the types of grossly inflated spreads at issue in this case, and says nothing about the policy objectives extant during the relevant period. Second, even if Medi-Cal's pharmaceutical reimbursement program had been designed to tolerate a modest and reasonable spread between reimbursement rates and pharmacists' actual acquisition costs, there is no evidence that the system was designed to allow the enormously inflated spreads that Defendants engineered for the purpose of marketing the products at issue—spreads which, in most cases, exceeded 300%. (*See* Declarations of Nicholas N. Paul, Exs. A (Nov. 19, 2009 Leitzinger Declarations), ¶ 6.[2])

Consequently, Defendants' reliance on *Independent Living Ctr. of S. Cal., Inc v. Maxwell-Jolly*, 572 F.3d 644 (9th Cir. 2009), and *Managed Pharmacy Care v. Maxwell-Jolly*, 603 F. Supp. 2d 1230 (C.D. Cal. 2009), is misplaced. The relevance of those decisions is confined to the facts that: (1) Medi-Cal has been continuously striving to save costs in accord with the statutory requirement of "economy"; (2) it is decidedly difficult for a complex system

[2] The Declaration of Nicholas N. Paul in Support of Plaintiffs' Motion for Partial Summary Judgment as to Defendants Dey, L.P. and Dey, Inc. (docket no. 6692), the Declaration of Nicholas N. Paul in Support of Plaintiffs' Motion for Partial Summary Judgment as to Defendants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (docket no. 6690) and Declaration of Nicholas N. Paul in Support of Plaintiffs' Motion for Partial Summary Judgment as to Defendant Sandoz Inc. (docket no. 6688).

like Medi-Cal to adjust its rates quickly and comprehensively; and (3) notwithstanding Defendants' enormous spreads, on the whole the system works reasonably well. These cases show, in fact, that Medi-Cal does not substantially overcompensate providers for drug acquisition costs, with the obvious exception being for the drugs at issue in this case. Indeed, in *Managed Pharmacy Care*, *supra*, the District Court found that a mere 5% reduction in pharmacy reimbursement would likely undercompensate pharmacy providers, primarily as to branded drugs which: (a) absorb 80% of Medi-Cal drug reimbursement, (b) do not exhibit the types of egregious mega-spreads implemented by Defendants, and (c) are not at issue in this case. *See id.* at 1239.[3]

A. California's Definition of "AWP"

Defendants myopically and incorrectly insist that California has historically and exclusively defined AWP as "the price for a drug product listed for a standard package in the Department's primary price reference source." Defendants further argue that because Medi-Cal has used other, more specific terms, such as Average Sales Price ("ASP"), the State has impliedly approved their practice of reporting AWPs that bore no relation to providers' actual acquisition costs. (Defs. Opp. at 3-5.) These arguments ignore not only the complete language of the pertinent regulation and statutes, but also this Court's prior rulings and common sense.

The 1989 regulatory record and the subsequent legislative history conclusively demonstrate that California policymakers used the term AWP in its plain meaning, i.e., as a means to estimate the cost of the drug products that pharmaceutical providers dispensed to

[3] Many drug companies report AWPs to Medi-Cal that are reasonably close to actual prices; indeed, the spreads on most products are well within the 25% margin that California has used for purposes of calculating its damages. The simple fact is that Defendants have deliberately abused the system, injuring taxpayers as well as Medi-Cal. The 2002 Myers & Stauffer report recommended that Medi-Cal consider reimbursing generic products at AWP minus 20 to 25%. Clearly, even that large a discount would not solve the problem of Defendants' spreads, which often exceeded 1000%. The only way to address such outrageous behavior is through enforcement actions, such as this case—not by reducing overall reimbursement rates at such extraordinary discounts that the rates fail judicial scrutiny and punish those manufacturers that report prices honestly.

program beneficiaries. Defendants' distorted definition requires the conclusion that California policymakers intended the term "Average Wholesale Price" to mean whatever numbers Defendants created and reported to First DataBank for their "standard package" drugs, even if those amounts were 10, 20, or 30 times the actual prices providers paid for their products. That is an absurd conclusion.

Defendants overlook the context in which the term AWP was used in Section 51513 and the relevant California statutes—specifically, as a means to arrive at an "estimated acquisition cost" of the relevant drug products. As this Court has previously noted:

> The federal Medicaid program requires state Medicaid programs that provide a prescription drug benefit to beneficiaries, such as Medi-Cal, to reimburse drug providers for their prescription products at the Cost of the Drug Product ("CDP"). CDP is defined as equal to the lower of the Estimated Acquisition Cost ("EAC"), the Federal Allowable Cost, the Maximum Allowable Ingredient Cost ("MAIC") for the standard package size, or the amount billed by the provider. *See* Cal. Code Regs. tit. 22, § 51513 *et seq.* (2006) (discussing how Medi-Cal reimburses drug providers). For purposes of determining CDP, the EAC for a drug product is set at the Direct Price ("DP") or the Average Wholesale Price ("AWP"), less a fixed percentage. Cal. Welf. & Inst. Code § 14105.45.
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> * * *
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> According to federal regulation, EAC represents the government's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.301 (2006).

In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d 164, 169 (D. Mass. 2007) (footnote omitted). The fact that AWP has been explicitly used as a means to arrive at the "estimated acquisition cost" and "cost of drug product" demonstrates that the term was intended to represent precisely what its plain meaning denotes—the average wholesale price at which Defendants' products were acquired by providers. And in denying Defendants' motion to dismiss, this Court firmly rejected their arguments that AWP could be simplistically understood to mean any amount that Defendants reported to pricing compendia, and that Defendants had no

duty to report good faith estimates of the actual average wholesale prices of their products. Specifically, the Court stated as follows:

> Plaintiff argues that its reliance on the compendia to determine reimbursement figures does not give the pharmaceutical companies free rein to falsify those numbers. Rather, the state argues the evident purpose of the law is that the state would be directed to rely on this compendium because it would provide "the best estimate of the price generally and currently paid by providers." Cal. Code Regs. tit. 22, § 51513(a). Plaintiff has the better argument. Defendants' interpretation that they have *carte blanche* to publish sky-high prices unmoored from the acquisition costs of providers leads to absurd results.

Id. at 173.

B. California's Understanding of AWP

Defendants claim that "[m]assive evidence in the record shows that California knew that published AWPs significantly exceeded costs for drugs, especially generic drugs such [sic] the Subject Drugs." (Defs. Opp. at 5.) This statement is not true to the extent it implies the type of knowledge required to exonerate Defendants' fraudulent actions; moreover, any generalized and imprecise perceptions California officials may have gradually developed regarding the inaccuracies of AWPs are irrelevant with respect to the purpose for which the term was employed in the governing regulation and statutes.

While Defendants recite various OIG and other reports, and even quote the comments of an unidentified "wholesaler representative," they consciously ignore the 1989 regulatory record regarding the revisions to Section 51513, which set the basic reimbursement rate that California used until late 2002. That extensive record makes it clear that the rulemakers understood and used AWP as a means to estimate providers' acquisition costs and expressly directed that "the

State must come as close as possible to the actual acquisition cost. The AWP-5% program is the State's best estimate of this cost." (CA SOAF Defs. ¶ 19.[4])

Although in later years California officials may have generally but imprecisely understood that there were problems with reported AWPs, there is no evidence that such officials had adequate information to appropriately restructure the pharmacy reimbursement system prior to late 2004, when they revised reimbursement based on the Myers & Stauffer report. The fact that the government may delay in acting to solve difficult matters, even when it has some knowledge of problems, does not constitute ratification of the underlying conduct. To the contrary, the various government studies and proposals show increasing concern that something was intrinsically corrupt in certain sectors of pharmaceutical pricing—not ratification of Defendants' reporting of grossly inflated AWPs. "That the government responded lethargically to the knowledge of fraud does not translate into approval." *Massachusetts v. Mylan Labs*., 608 F. Supp. 2d 127, 151 (D. Mass. 2008). As the First Circuit held: "On balance, we read the legislative history and statutory context to be one of slow adaptation to shadowy industry practices, not ratification of them." *In re Pharm. Indus. Average Wholesale Price Litigation*, 582 F.3d 156, 171 (1st Cir. 2009).

C. The 1987 Federal Regulations

Defendants distort the import of the 1987 revisions to the federal regulations governing Medicaid reimbursement. The revisions gave states greater flexibility in structuring their Medicaid pharmacy programs and expressly allowed state agencies to reimburse more for specific drugs within each of two broad categories: (a) brand drugs and generics not covered by Federal Upper Limits ("FULs"); and (b) drugs covered by FULs—as long as those higher

[4] All references to "CA SOAF Defs." refer to Plaintiffs' Statement of Additional Undisputed Facts in Opposition to Defendants' Motions for Partial Summary Judgment (docket no. 6790).

payments were offset by lower payments for other drugs within that category. *See* 147 FED. REG. 28648-58 (July 31, 1987). The revised regulations required state Medicaid programs to reimburse providers at *no more than* their estimated acquisition costs plus a reasonable dispensing fee for most drug products (on an aggregate basis) or, for products covered by FULs, at *no more than* the FULs set by HCFA plus a reasonable dispensing fee (on an aggregate basis). 42 C.F.R. §§ 447.331(b), 447.332(b) (1987). Since FULs were to be set at 150 percent of the published price for the least costly therapeutic alternative, the regulation permitted states to pay a modest margin over estimated acquisition costs to encourage generic substitution. *Id.* The overriding reimbursement principle was that states should, in the aggregate, reimburse Medicaid providers no more than their estimated acquisition costs plus a reasonable dispensing fee.

Here, the critical fact is that California decided *not* to reimburse providers for drug products on an aggregated basis and *not* to reimburse for generic products at their FULs, if those FULs exceeded providers' estimated acquisition costs. Instead, the California regulation expressly limited reimbursement to *the lesser of* each drug product's FUL (identified in the 1987 California regulation as the Federal Allowable Cost, or FAC) or its EAC, stating:

> Cost of the Drug Product . . . means the lowest of the Estimated Acquisition Cost (EAC), the Federal Allowable Cost (FAC), or the Maximum Allowable Ingredient Cost (MAIC) . . . for the Standard Package Size.
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> * * *
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> Payment for legend generic drug types dispensed by licensed pharmacists in compliance with Section 51513 shall consist of the cost of the legend generic drug type dispensed, plus a professional fee for services.

CAL. CODE REGS. tit. 22, § 51513(a)11, (b)(1).

In short, except for its pre-2002 reimbursement for certain (non-Defendant) manufacturers' products at "direct price," California continued to use a unitary reimbursement formula for all drug products—brand and generic. That formula continued to limit

reimbursement for all drug products, including generic drugs, to their estimated acquisition cost. To this end, the Final Statement of Reasons accompanying revised Section 51513 in 1987 (the revisions of which were intended to adapt to the 1987 Federal revisions) states that "[t]he actual reimbursement formula, based on the state's definition of estimated acquisition cost plus a fixed dispensing fee, has not changed." (Robben Decl.[5] Ex. 17 at 7.) California thus continued to limit reimbursements for drug products to their estimated acquisition costs (which were based on reported AWPs).

D. California's Policy Decisions Concerning Reimbursement

In Defendants' rendition of California's alleged "policy decisions concerning reimbursement," they fail to address either the language of the 1989 regulation or the extensive regulatory and statutory record. Defendants instead discuss a 1986 HCFA study, a 1996 report from OIG, California's purported failure to adopt the 2000 DOJ AWPs, and Defendants' skewed interpretation of the 2002 and 2004 statutory changes in California's reimbursement policy. The 2002 statutory changes were implemented before the Legislature had the benefit of the Myers & Stauffer report, and the 2004 statutory changes included other mechanisms intended to address the problem of inflated generic prices, which explains why the Legislature did not adopt a lower reimbursement rate for generic drugs. (CA SOAF Defs. ¶¶ 23-24.) The policy decisions in 2002 and 2004 were made by the Legislature, and the only appropriate means by which to understand the Legislature's decisions are (1) the statutory language and (2) the relevant legislative history. *Quintino v. Mercury Cas. Co.*, 11 Cal. 4th 1049, 1061-63 (1995). Further, as discussed above, the meaning and import of those statutory changes is a question of law, not a question of fact.

[5] Declaration of Philip D. Robben in Support of Defendants' Motions for Partial Summary Judgment (docket no. 6702).

E. Ninth Circuit Injunctions Against Reimbursement Rate Reductions.

The Ninth Circuit has held that California is required, under federal law, to base changes in Medicaid reimbursement rates on rate studies, and that the State's budgetary woes do not in themselves justify reductions in Medicaid reimbursements. However, the underlying decisions in *Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491 (9th Cir. 1997), and *Independent Living Center*, 572 F.3d 644, cannot bear the weight Defendants place on them. Those decisions illustrate the complexities of the Medi-Cal system and the difficulties and delays inherent in altering it, but not, as Defendants contend, that California deliberately relied on a "reimbursement methodology it knew paid providers more than their actual costs . . . ." Defendants' contrary argument rests on the myth that government delay constitutes a deliberate and intentional endorsement of the status quo. As previously noted, that is not consistent with law or reality. *See In re Pedro T.*, 8 Cal. 4th 1041, 1048 (1994) ("[T]o seek a hypothetical legislative intent at some time after enactment of the statute would seem necessarily to disregard the probable legislative intent at the time of the enactment. We are directed to no authority sanctioning such an approach.").

ARGUMENT

I. DEFENDANTS HAVE FAILED TO PRESENT A GENUINE ISSUE OF MATERIAL FACT CONCERNING CAUSATION.

A. Defendants' "Government Knowledge" Argument Fails to Demonstrate A Causation Issue.

Defendants attempt to escape the inherent weaknesses of their government knowledge defense by recasting it as a causation issue. They remain obligated, however, to demonstrate that the defense actually applies—i.e., that the "government [possessed] knowledge of the actual true facts of the claim, not simply knowledge that the claim is generally false," *Mylan Labs.*, 608 F. Supp. 2d at 148,; and that California formally, publicly and affirmatively approved of the alleged wrongful price reporting conduct. *See, e.g.*, *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir.

2004) ("agency interpretations are only relevant if they are reflected in public documents . . . . The non public or informal understandings of agency officials concerning the meaning of a regulation are thus not relevant.").

Defendants have not presented evidence showing that California ever implemented a policy that expressly approved Defendants' practices of reporting grossly inflated AWPs. Nowhere do Defendants direct the Court to official policy statements, regulatory or statutory authority, or other official pronouncements that show ratification or approval of their false reporting practices.[6]

California would have been remiss had it not sought to meet the standards of Section 30(A) of the Medicaid Act, as interpreted in *Orthopaedic Hospital*, 103 F.3d 1491. As Defendants implicitly concede in their opposition—and as would be expected from a government agency attempting to comply with the law—California has doggedly strived to meet its obligations as set forth by statute and regulation and as interpreted by the courts. During the relevant period, both the findings of *Orthopaedic Hospital* and the budgetary concerns and fiscal constraints faced by Medi-Cal were integral to its operation of the biggest Medicaid program in the country. But as the damages computations by Plaintiffs' expert witness make clear, the pernicious impact of Defendants' fraudulent AWPs on Medi-Cal's multibillion dollar prescription drug reimbursement program was another key factor impacting Medi-Cal expenditures. Certainly no California policymaker ever approved of or ratified Defendants' unlawful conduct. In other words, Defendants' fraudulently inflated AWPs not only caused the

[6] Indeed, if, as Defendants insist, California had formally and knowledgeably approved of Defendants' fraudulently and grossly inflated AWPs in order to maintain provider participation and beneficiary access, then conspicuously absent from Defendants' briefing is any evidence demonstrating the myriad policy statements, interim directives, memorandums of understanding, legislative proposals, and other indicia of formal policy implementation which the Court should reasonably expect as evidence of such a policy. No reasonable jury could find that such a bizarre policy could have existed for over a decade within the largest state Medicaid program in the country, in the absence of evidentiary support.

overpayments claimed by California, but also, as observed by Medi-Cal Chief Deputy Director Stan Rosenstein, inescapably contributed to California's ongoing need to "fix" a reimbursement methodology that would not otherwise have needed "fixing." (CA SOAF Defs. ¶¶ 12-14.) Defendants therefore find themselves in the awkward position of seeking to defeat causation in this action by attacking and mischaracterizing the ameliorative efforts undertaken by California to compensate for Defendants' inflated AWPs, while studiously ignoring the fact that a jury could not help but find that Defendants and other manufacturers like them were largely the reason those ameliorative efforts were necessary in the first place.

B. The Manner by Which FULs Were Set is Immaterial as to Whether Defendants' Fraudulently Reported AWPs Caused Overpayments by Medi-Cal

Defendants stubbornly refuse to abandon their untenable argument that all claims for drugs reimbursed on a FUL are not actionable due to alleged attributes of CMS's FUL-setting process. However, as set forth in Plaintiffs' Opposition to Defendants' Joint Brief in Support of Their Motion for Partial Summary Judgment,[7] because California employs a "lesser of" formula that includes AWP as an integral component of each and every claim at issue in this case, *see* CAL. WELF. & INST. CODE § 14105.45, when Defendants published false AWPs they ensured that any provider claims seeking reimbursement for Defendants' drugs would also be false. Plaintiffs' damages expert, Dr. Leitzinger, has established the extent to which Defendants' "but for" or "real" AWPs for the Subject Drugs were below their associated FULs or their Usual and Customary prices.[8]

[7] S*ee* Plaintiffs' Opposition to Defendants' Joint Brief in Support of Their Motions for Partial Summary Judgment (docket no. 6789) (hereinafter, "Pls. Opp. to Defs. Jt. SJ Br.") at 27-30).

[8] As further explained in Plaintiffs' Opposition to Defendants' Joint Brief in Support of Their Motion for Partial Summary Judgment, Plaintiffs also reject Defendants' characterization that CMS was inconsistent in the manner in which it set FULs. (*See* Pls. Opp. to Defs. Jt. SJ Br. at 29.) CMS relied on manufacturer WACs in setting FULs, unless a particular WAC was so low that officials determined it was a data "outlier" and therefore an unreliable basis

C. That Defendants Had No Control Over Medi-Cal's Reimbursement Methodology is Immaterial.

In support of their causation argument, Defendants protest that they played no role in the creation or administration of California's reimbursement methodology or policy. (Defs. Opp. at 15-16.)

At all times it has been California's prerogative to select whatever reimbursement methodology it deems appropriate, so long as it comports with federal standards. To the extent that they wished to ensure their drugs were covered by Medi-Cal's prescription drug reimbursement program, Defendants had the obligation to know, understand, and comply with Medi-Cal's properly authorized policies, including those concerning reimbursement. *See, e.g.*, *Heckler v. Community Health Services of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984); *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001); *North Mem'l Med. Ctr. v. Gomez*, 59 F.3d 735, 739 (8th Cir. 1995). During the relevant period, California, like a grand majority of state Medicaid programs across the country, chose to reimburse prescription drugs on the basis of several appropriate pricing metrics, including AWP. Not surprisingly, Defendants have failed to reference any authority for the proposition that they were ever *e*entitled to control any aspect of California's reimbursement methodology. As such, Defendants were required to deal honestly and fairly with Medi-Cal by reporting AWPs that had at least some reasonable relationship to the providers' estimated cost of acquisition. They did not.

II. PLAINTIFFS HAVE ESTABLISHED FALSITY AS A MATTER OF LAW AND UNDISPUTED FACT.

Defendants' argument that a clear "objective standard" is necessary for assessing whether a reported AWP is "false" is an argument that has been made, and rejected, many times by this

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on which to set the FUL. (CA SOAF Defs. ¶¶ 26-28.) CMS manually intervened under just two limited circumstances, both of which removed data errors or inconsistencies so as to ensure the FUL setting process operated properly. (CA SOAF Defs. ¶ 33.)

Court[9] and by the First Circuit.[10] Under the theory espoused in Defendants' Opposition (Defs. Opp. at 18-19), where Defendants advance a meaning of AWP specifically rejected in this case by this Court,[11] there would be no restraints on their AWP inflation. As Defendants tellingly insist: "California never defined AWP in a statute or regulation as anything other than a price that appeared for a particular drug in a pricing compendia, which is what Defendants' AWPs are. See Joint SOF at ¶ 20. On this criterion, there is no basis to hold that Defendants' AWPs were false." (Defs. Opp. at 19.) If Defendants' warped interpretation of California's straightforward regulatory structure was correct, then it necessarily follows that none of the prices reported by Defendants could ever be deemed false. This standard abjures any responsibility for reported prices; literally, anything goes. Not surprisingly, Defendants have cited no authority for the proposition that a statute or regulation that uses an undefined term will be deemed to have no meaning whatsoever.

Courts have consistently held that undefined terms in a statute or regulation are normally given their plain meaning, absent a clear and compelling showing that the resulting interpretation would lead to absurd results. This Court has previously applied a plain meaning definition to the term AWP in the contemporaneous Medicare statute, and to the term WAC in the Massachusetts Medicaid program. *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277,

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[9] *See, e.g., In re Pharm. Indus. Average Wholesale Price Litig*., 478 F. Supp. 2d at 174 ("The drug prices alleged by plaintiff cross any reasonably drawn line between estimates which reasonably reflect prices paid by providers and estimates which are so grossly inflated when compared to actual acquisition costs that they are by their very nature fraudulent."); *Id*. at 173-74 ("sky-high prices unmoored from the acquisition costs of providers" are "false" for purposes of the FCA); *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d 20, 103, 105-08 (D. Mass. 2007); *In re Pharm. Indus. Average Wholesale Price Litig*, 520 F. Supp. 2d 267, 270 (D. Mass. 2008).

[10] *See In re Pharm. Indus. Average Wholesale Price Litigation,* 582 F.3d at 170 ("We also share the district court's concern that Congress "could not have intended AWP to be a term of art for whatever price the industry chose to put in the industry publications," for that would "give the pharmaceutical industry free reign over drug pricing," and permit the industry to post AWPs "without any connection to prices in the market." This 'absurd outcome' provides an additional, independent reason to reject AstraZeneca's purported technical definition.")

[11] *In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d at 173-74.

287 (D. Mass. 2006) (holding that "the term 'average wholesale price' in the Medicare statute is not a term of art for any price the pharmaceutical industry places in the industry publication and will be construed under the plain language doctrine of statutory construction"), *aff'd, In re Pharm. Indus. Average Wholesale Price Litig.* 582 F.3d at 170; *Mylan Labs.*, 608 F. Supp. 2d at 143-144. The same reasoning compels an identical conclusion as to the meaning of the term AWP in the Medi-Cal program. As in the federal context, the term AWP is used as a reference point for the determination of a rate for drugs to be reimbursed by a government medical program. As in the federal context, the structure of California's drug reimbursement program is to reimburse providers for drugs at or near the acquisition cost of those drugs. As in the federal analysis, review of the world of pharmaceutical pricing would show that there was, in fact, no hard-and-fast industry understanding of AWP, thus defeating any notion that the term should be considered an industry term of art.

Under much the same analysis, in *Mylan Labs* this Court determined that WAC should be given its plain meaning definition in the context of the Massachusetts Medicaid program. In support of that conclusion, the Court found that WAC was used to determine estimated acquisition cost for drug products, which was the governing standard in the state's Medicaid program. The Court reasoned as follows:

> EAC is meant to estimate what pharmacies actually pay for drugs. WAC plus a percentage is used to calculate EAC. Thus WAC must be the type of thing that is amenable to being used to estimate what pharmacies actually pay for drugs. The price that wholesalers actually pay for drugs is just such a term; simply add a percentage adjustment to account for the wholesalers' overhead and profits and, voila, you can estimate what pharmacies actually pay for drugs. If, on the other hand, WAC were understood to mean merely a list price, a price set by manufacturers and listed at the top of invoices but rarely paid by wholesalers, then WAC could not be used to accurately estimate what pharmacies actually pay for drugs without significant additional information.

Mylan Labs., 608 F. Supp. 2d at 143-144. The same analysis is applicable here, since Medi-Cal similarly uses AWP to estimate acquisition cost. Furthermore, even without the benefit of this Court's prior conclusion that the "plain meaning" of AWP is "the average price at which wholesalers sell drugs to their customers,"[12] a straightforward reading of the applicable regulations makes clear that since the term AWP was used by the government as a means to estimate pharmaceutical providers' actual acquisition costs,then reported and published AWPs must be sufficient to permit this estimated acquisition cost function to be performed accurately.

Defendants nevertheless insist that a term that is not precisely defined in a statute or regulation—even if that term is interpreted by a court in the context of litigation—simply cannot be the basis for false claims act liability because the "ambiguity" in the language precludes any finding of knowing conduct, as required under the Act. This argument, too, has been repeatedly rejected; instead, courts have concluded that only a *reasonable* interpretation of an ambiguous regulation may defeat FCA liability. *See, e.g., United States v. Science Applications Int'l Corp.*, 653 F. Supp. 2d 87, 97 (D.D.C. 2009) ("defendant's reasonable interpretation of an ambiguous regulation may well be a successful defense to an alleged FCA violation in appropriate cases"); *United States ex rel. Fry v. Health Alliance of Greater Cincinnati*, 2009 WL 485501, *6 (S.D. Ohio Feb. 26, 2009) ("The Court simply does not find that the alleged pay to play kickback scheme could comport with an objectively reasonable reading of the text of the relevant statutes."); *United States ex rel. El-Amin v. George Washington Univ.*, 2005 WL 3275997, *5-*6 (D.D.C. Aug. 31, 2005) (defendant's interpretation of ambiguous regulation must be plausible or reasonable in order to defeat scienter under FCA).[13]

[12] *In re Pharm. Indus. Average Wholesale Price Litig*., 460 F. Supp. 2d at 278.

[13] Defendants' cited cases are not to the contrary. In *United States ex rel. Local 342 Plumbers & Steamfitters v. Caputo Co.*, 321 F.3d 926 (9th Cir. 2003), for example, the court reviewed a complex labor situation in which there

Eschewing this case law, Defendants essentially propose that the government may not bring any action for false and fraudulent claims whenever the underlying substantive law does not precisely define all the incorporated terms. Notably, Defendants do not, and cannot, contend that they reported prices which either permitted reasonable estimates of acquisition costs or constituted a coherent measure of prices generally and currently paid by providers for their products. Notwithstanding the clear mandate in the Medi-Cal reimbursement methodology that AWPs were being used to determine estimated acquisition cost (which, as stated, is defined by the State as the "price generally and currently paid by providers"), Defendants admit that they did not report AWPs that met any reasonable, plain meaning definition of the term average wholesale price or reflected prices generally and currently paid by providers for their drugs.

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was a dispute as to whether the defendant had properly paid the prevailing wage. *Id.* at 933. Unlike the instant case, however, the term "prevailing wage" had a very specific meaning and administrative process for determination pursuant to regulations and case law. The False Claims Act case was dismissed not because there was no definition of the term, but because there had been no determination of the prevailing wage pursuant to the definition of the term. *Id.* at 933. As the court held, "[t]he May 1992 agreement of the Laborers and the Plumbers did not establish a prevailing wage, as the agreement was not followed [invoking explicit regulatory provision that agreement could not establish a prevailing wage absent evidence the agreement was followed]. No prevailing wage or classification of work was established by any actual survey. No prevailing wage or classification was established by any collective bargaining agreement, the second way Roen I held a prevailing wage might be established. No prevailing wage was established by the three Conte-Davis letters, the second superseding the first, and third superseding the second, with Conte's conclusions finally being repudiated by his superior." *Id.* In *United States ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022 (S.D. Iowa 1998), the case was dismissed for lack of specificity under Rule 9(b). *Id.* at 1025. The dispute in the case turned on whether billing for air ambulance transport was supposed to have been done in nautical miles or statute miles. Because that determination was not clear, the court rejected the false claims act suit on the alternative ground of lack of falsity. *Id.* at 1026. No one argued, however, that it would have been permissible for the defendant to have billed in Martian miles, which would be the equivalent to defendants' arguments herein. Finally, in *United States v. Prabhu*, 442 F. Supp. 2d 1008 (D. Nev. 2006), the ultimate factual conclusion made by the district court was that "the undisputed facts reflect that for thirteen years Medicare advised Dr. Prabhu that he was allowed to bill for the simple stress test component of pulmonary rehabilitation services." *Id.* at 1032. Further, the court found that there was "no dispute that services were provided and those services were clinically medically necessary and indicated," meaning that the best case the government could make was that approximately 5% of the alleged claims had possible documentation errors, which were themselves unclear due to ambiguous standards. *Id.* at 1033. Tellingly, although not cited by these Defendants, the court in Prabhu clearly articulated a standard regarding falsity: "To establish falsity under the FCA, it is not sufficient to demonstrate that the person's practices could have or should have been better. Instead, plaintiff must demonstrate that an objective gap exists between what the Defendant represented and what the Defendant would have stated had the Defendant told the truth." *Id.* (emphasis added). As this Court has already determined, and as the undisputed prices establish, there is an enormous "objective gap" between the reported prices and the actual prices. *In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. at 174 ("The drug prices alleged by plaintiff cross any reasonably drawn line between estimates which reasonably reflect prices paid by providers and estimates which are so grossly inflated when compared to actual acquisition costs that they are by their very nature fraudulent.")

Indeed, Defendants expressly stated that they set, reported and maintained AWPs at prices which were 10% below the reported AWPs for the brand version of their products, or were based on some competitors' then-existent AWPs. (*See* CA Dey SOF[14] ¶¶ 8, 9; CA Mylan SOF ¶¶ 7-9; CA Sandoz SOF ¶¶ 7-9.) Defendants knowingly failed to update their AWPs in accordance with the declining prices that characterized the market for their drug products, but raised AWPs for their products when it appeared that doing so would facilitate sales. Defendants acted with full knowledge that the prices they reported as AWPs would be used for Medi-Cal reimbursement purposes[15] and would lead to greater reimbursement payments than AWPs which were reflective of the actual prices paid by providers. Moreover, Defendants knew, both as a matter of general business practice and specifically for each product, that their market prices declined significantly and quickly after launch, and thus could not be merely 10% less than the brand reported AWP. (*See* CA Dey SOF ¶¶ 10-12; CA Mylan SOF ¶¶ 10-12; CA Sandoz SOF ¶¶ 10-12.) Accordingly, there are no genuine issues of material fact as to the falsity of the AWPs which Defendants knowingly reported to California's Medi-Cal program.

III. DEFENDANTS CANNOT DEMONSTRATE A QUESTION OF FACT REGARDING THEIR SCIENTER.

There are no genuine issues of material fact as to Defendants' scienter. To establish liability, California need not show that Defendants acted intentionally, but merely that they acted with actual knowledge, deliberate ignorance, or reckless disregard of the relevant information when they reported false AWPs to the compendia. *See* CAL. GOV'T CODE § 12650(b)(2). Plaintiffs have handily met this standard. Because Defendants' arguments as to their asserted

[14] All references to "CA Dey SOF," "CA Mylan SOF," or CA Sandoz SOF" refer to California's Local Rule 56.1 Statement of Undisputed Material Facts as to Defendant _____" (docket nos. 6691, 6689, 6687 respectively).

[15] As discussed previously, it was plainly established in California reimbursement methodology that payment would be made at the "lower of" a FUL, if it existed, or the published AWP. For each claim paid, therefore, the reported AWP entered into the determination of the amount to be paid, even where a FUL was actually selected as the basis for payment on particular claims.

lack of scienter rest upon "conclusory allegations, improbable inferences, and unsupported speculation," *Mylan Labs.*, 608 F. Supp. 2d at 154, this Court should reject such arguments and grant summary judgment for Plaintiffs.

A. California Has Established Defendants' Scienter as a Matter of Law.

Defendants' argument that "issues of fact abound as to scienter since Defendants never understood that California intended AWPs to be an approximation for providers' actual acquisition costs" does not raise a genuine issue of material fact. (Defs. Opp. at 23-24.) First, as a matter of law, Defendants' purported misunderstanding of the term AWP, even if true, does not make out a defense. The Government Code clearly defines the mental state necessary to make out a violation of the False Claims Act:

> (2) "Knowing" and "knowingly" mean that a person, *with respect to information,* does any of the following:
> (A) Has actual knowledge *of the information*.
> (B) Acts in deliberate ignorance of the truth or falsity *of the information*.
> (C) Acts in reckless disregard of the truth or falsity *of the information*.
> Proof of specific intent to defraud is not required.

CAL. GOV'T CODE § 12650 (emphasis added). To prove its claim, California need only establish that Defendants knew that the information they reported as their average wholesale prices was false. Their apparent misunderstanding as to the law is irrelevant. *See Brown v. Board of Med. Qual. Assur.*, 86 Cal. App. 3d 548, 555 (1978); *cf. People v. Gregory,* 217 Cal. App. 3d 665, 672 (1990) (vagueness of regulation is only a defense when specific intent to defraud is required). Liability under the California FCA does not require a deliberate lie. A defendant entitiy is liable where it has actual knowledge of the relevant *information* or acts with deliberate ignorance or reckless disregard of the truth or falsity of the *information* it provides. *See Thompson Pacific Construction, Inc. v. City of Sunnyvale*, 155 Cal. App. 4th 525, 549 (2007). Hence, Defendants are clearly liable here.

Second, Defendants ignore the fact that, as discussed above, the California regulation expressly used reported AWPs as a means to determine providers' estimated acquisition costs for Defendants' drug products. Any possible doubt Defendants may have had about the meaning of the term AWP would have been eliminated by simply reading the regulation. Moreover, by electing to participate in Medi-Cal, Defendants were required to familiarize themselves with the legal requirements, standards, and procedures of the program. *See, e.g., Heckler v. Community Health Services of Crawford Cty., Inc.*, 467 U.S. at 64; *United States v. Mackby*, 261 F.3d at 828. Hence, as a matter of law, Defendants are charged with the knowledge that California used their reported AWPs to determine EAC—which was "the department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package." CAL. WELF. & INST. CODE § 14105.45(a)(4) (West 2009). And, as this Court previously found:

> The drug prices alleged by. . . [California] cross any reasonably drawn line between estimates which reasonably reflect prices paid by providers and estimates which are so grossly inflated when compared to actual acquisition costs that they are by their very nature fraudulent.

In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d at 174.

B. Defendants' Purported Misunderstanding As to the Meaning of AWP Is Not a Defense.

As discussed above, Defendants were charged with educating themselves as to the requirements of the Medi-Cal program, and their purported misunderstanding as to the meaning of the term AWP is not a defense. Moreover, as a matter of law, Defendants fail to make out the limited circumstances under which a good faith misunderstanding of their legal obligations might constitute a defense to scienter under the FCA. *See United States v. Bourseau,* 531 F.3d 1159, 1167-68 (9th Cir. 2008); *Thompson Pacific,* 155 Cal. App. 4th at 549.

First, Defendants' argument that they "understood that, for generic drugs, AWP was an undiscounted benchmark price that was set in relation to published prices for therapeutically equivalent [brand] drugs" (Defs. Opp. at 26) is inconsistent with the plain meaning of the term AWP. This Court has previously found that California's use of the term AWP is consistent with the term's "plain meaning." Indeed, it would have entirely undercut Medicaid's rationale for mandating or encouraging the use of generic drugs if all such drugs were routinely priced at 90% of the equivalent brand product.

Second, given that Medi-Cal used Defendants' AWPs to calculate EAC, which was defined as an estimate of what pharmacies pay for drugs, a reasonable trier of fact would necessarily conclude that Defendants recklessly disregarded or were deliberately ignorant of the fact that they were meant to report an AWP suitable for such estimation—that is, a price which bore some reasonable relationship to prices that were generally and currently being paid by providers. Moreover, it is noteworthy that Defendants never informed federal or California officials of their purported contrary understanding of the term, much less sought or obtained any formal or informal approval of their practice of reporting AWPs calculated in this manner. *See Commercial Contractors, Inc. v. United States,* 154 F.3d 1357, 1366 (Fed. Cir. 1998) ("when the contractor's purported interpretation . . . borders on the frivolous, the contractor must raise the interpretation issue with the government contracting officials or risk liability under the FCA").

Third, all of the OIG and other reports that Defendants rely on for their "government knowledge" defense decry the "spread" between actual acquisition costs and reported AWPs. There would be no reason for those governmental concerns had AWPs reasonably approximated provider acquisition costs. Defendants cannot reasonably argue that they believed that reporting AWPs which were 5, 10, or 20 times the providers' actual acquisition costs, was consistent with

the California rule and statute. Defendants' supposed understanding of the term AWP lacks any reasonable basis and does not negate Plaintiff's overwhelming evidence as to Defendants' scienter.

Defendants' individual attempts to negate scienter also lack merit. Sandoz concedes that its AWPs "were not intended to be actual average prices" (Defs. Opp. at 26), but tries to rely on the fact that other numbers it reported, such as WACs and AMPs, were more accurate. Even assuming the veracity of their other pricing metrics, Sandoz was nonetheless required to accurately report the AWPs it knew, as a matter of law or fact, California used for reimbursement purposes. The fact that other prices it reported were more accurate is no defense. California had no obligation to audit Sandoz's AWPs and compare those amounts to other prices the Company reported. Indeed, the fact that Sandoz knew that its AWPs were irreconcilable with other prices it calculated and reported demonstrates its culpability.

Similarly, Defendants Mylan and Dey argue that their disclosure of WACs and AMPs belies any notion that Defendants were "keeping [their] actual transaction prices a secret." (Defs. Opp. at 28, 30.) But California's claims are not predicated on whether Defendants kept their actual transaction prices a secret; again, in fact, Defendants' concession that they knew of the huge disparity between their actual transaction prices and reported AWPs spotlights their liability. California's purported ability to ferret out Defendants' actual transactional prices is irrelevant, particularly where, as here, the reimbursement rate was fixed by regulation and statute and Medi-Cal officials had no ability to change that formula. In light of their imputed knowledge of Medi-Cal's reimbursement methodology, Defendants' struthious behavior in relying on their own implausible interpretation of how AWPs should be computed is the very

model of "deliberate ignorance of the truth or falsity of the information" identified in the FCA. Accordingly, Defendants' specious claims do not preclude a finding of scienter.

Finally, Defendants argue that their failure to follow the law should be excused by Medi-Cal's purported knowledge regarding the inaccuracies of reported AWPs. But, as Plaintiffs have discussed at length, Defendants do not make out the requirements of the "government knowledge" defense. For example, Mylan relies on a July 17, 2002 email from Medi-Cal official Mike Namba to Eric Belldina in which Mr. Namba provides hypothetical examples of supplemental rebate calculations. In his email, Mr. Namba writes, "[s]ince the AWP is inflated, the manufacturer must rebate a very large amount to reach the net price." (Defs. Opp. at 29; Palermo Decl. Ex. S and T.[16]) Mylan's argument to the contrary notwithstanding, this email and its attachments could not reasonably be interpreted by a jury as an "instruction" regarding the setting or reporting of AWPs; rather, it simply illustrates how Medi-Cal would calculate supplemental rebates on a product.[17] Further, as discussed further in Plaintiff's Opposition to Defendants' Joint Motion for Summary Judgment, it is well-settled law that any arguable knowledge on the part of agency personnel cannot negate falsity or scienter where, as here, the claims arise from violations of a non-discretionary regulatory or statutory standard. (*See* Pls. Opp. to Defs. Jt. SJ Br. at 21-27.)

[16] Declaration of Christopher C. Palermo in Support of Defendants Mylan Inc. and Mylan Pharmaceutical Inc.'s Opposition to Plaintiffs' Motion for Partial Summary Judgment (docket no. 6798).

[17] Notably, the email concerns Estradiol Transderm, a drug product manufactured by *non*-Defendant Mylan Technologies, is not identified as a Subject Drug. Furthermore, since 1996, none of Defendant Mylan Pharmaceutical's drug products were subject to supplemental rebates. Indeed, in general, there were very few generic products subject to such rebates. Thus, the email and its attachments are irrelevant to any of the issues before the Court. Notably, the email concerns Estradiol Transderm, a drug product manufactured by *non*-Defendant Mylan Technologies, is not identified as a Subject Drug. Furthermore, since 1996, none of Defendant Mylan Pharmaceutical's drug products were subject to supplemental rebates. Indeed, in general, there were very few generic products subject to such rebates. Thus, the email and its attachments are irrelevant to any of the issues before the Court.

In addition to the fact that Mr. Namba had no say over legislatively determined reimbursement rates, the 2002 email came relatively late in the day, when there was widespread knowledge of inflated AWPs, which California was in the process of addressing through both the instant litigation and changes to its reimbursement methodology. Further, Mylan presents no evidence that it ever relied on the 2002 Namba email when inflating its AWPs. Indeed, Mylan's explanation of how it actually set AWPs makes its "government knowledge defense" nonsensical.

Nothing in the record before the Court even remotely suggests that California's method and practice of collecting supplemental rebates in any way constituted acquiescence or ratification of Defendants' submission of false and inflated AWPs. It is simply disingenuous for Mylan to argue that Medi-Cal's efforts to reduce its expenditures through supplemental rebates should be interpreted as an act of acquiescence or ratification of its inflated AWPs.

Similarly, Dey's observation that in 1999 it began sending to Medi-Cal letters indicating that its AWPs did not represent *actual* wholesale prices merely demonstrates Dey's liability. These self-serving and vague letters were entirely inadequate to properly disclose to California that Dey was unlawfully reporting grossly inflated AWPs to the compendia. Moreover, California never informed Dey that its fraudulent AWPs were in any way acceptable. Rather, as shown by Plaintiffs in their moving papers, applicable statutory and regulatory history make clear that California officials consistently used the term AWP in an effort to estimate the prices generally and currently paid by providers for pharmaceutical products. (*See* Plaintiffs' Memorandum in Support of Motion for Partial Summary Judgment ("Pls. SJ Br.") (docket no. 6686) at 7-9.)

The fact that the government, over time, developed an imperfect understanding that there were irregularities concerning reported AWPs carries no weight. As this Court observed in *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 582 F.3d 156 (1st Cir. 2009), courts "[which] have found that government knowledge can prevent the defendant from forming the requisite state of mind (knowing that the claim is false or fraudulent) *have done so only where the government's knowledge as to the true facts is extensive and in some cases where the government has actively approved of the underlying facts.*" *Id.* at 171 (emphasis added). Defendants fail utterly to demonstrate that they disclosed to the government the true extent of the facts underlying the FCA claims. Accordingly, their attempt to circumvent a finding of scienter under the theory of government knowledge is without merit.

Ultimately, the government did not and "could not have intended AWP to be a term of art for whatever price the industry chose to put in the industry publications," for doing so would "give the pharmaceutical industry free reign over drug pricing." *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 170. Nothing supports Defendants' arguments that they acted in good faith when they ignored the plain language of the regulations and defined reported AWPs in a manner that suited their business needs. As such, their respective claims concerning scienter simply do not raise genuine issues of material fact that warrant trial.

IV. DEFENDANTS HAVE FAILED TO ASSERT A VIABLE GOVERNMENT KNOWLEDGE DEFENSE.

A. Defendants Cannot Defeat Summary Judgment By Blaming The State For Its Reimbursement Methodology.

Defendants argue that California's choice of reimbursement framework/system, which includes AWP as a benchmark under the State's "lowest of" estimated acquisition cost methodology, vitiates California's claims because the State did not alter its reimbursement policy notwithstanding indications that AWPs were inflated. (Defs. Opp. at 31-34.) Aside from its

legal deficiencies, this argument starkly frames Defendants' simplistic defense—*viz*., "you left the door unlocked."

Defendants further argue that the State's programmatic or legislative efforts to understand the impact and extent of their AWP fraud allegedly works to their advantage in that such efforts negate Defendants' scienter on the grounds of government knowledge. This is a blatantly specious assertion. The underlying evidence of state and federal concern regarding AWP can only be seen as evidence of still more resources needlessly consumed, and costs incurred, by California and the United States directly resulting from Defendants' fraud.[18]

There is no precedent in either federal or California case law for the extraordinary proposition that the State is somehow precluded from seeking redress for fraud on the public fisc when it refrained from abandoning one payment methodology in favor of another, simply because it might, hypothetically, have been less prone to the degree of fraudulent abuse now in evidence.[19] The State's hypothetical ability to adopt alternative methodologies, with respect to estimating the ingredient cost of a drug or setting a FUL or a MAC, is utterly irrelevant. Nor is there any precedent for the proposition that Medi-Cal, which was processing millions of drug claims per month during the relevant period, should have abandoned its overarching payment

[18] The California Myers & Stauffer reports cost between $400,000 and $500,000 dollars, paid for by California and federal government monies. (*See* Declaration of Nicholas N. Paul in Support of Plaintiffs' Opposition to Defendants' Motions for Partial Summary Judgment (docket no. 6791), Ex. 4 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 312:20-313:9.) As recognized by the Court, HHS's Office of Inspector General devoted considerable resources in its attempt to understand the costs actually being incurred by providers and suppliers when obtaining drugs covered by Medicare and Medicaid. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 41-44.

[19] As this Court previously noted, HHS OIG's Pharmaceutical Guidelines released in 2003 "defeat any notion that the federal government's failure to change the AWP pricing benchmark signaled acquiescence in spread-marketing or the reporting of mega-spreads." *In re Pharm. Indus. Average Wholesale Price Litig*, 491 F. Supp. 2d at 95. *See also In re Pharm. Indus. Average Wholesale Price Litig*., 460 F. Supp. 2d at 285 ("The weight of the legislative history reflects congressional intent to have the AWP moored to actual wholesale pricing, and a nagging concern that AWP was no longer a reasonable price."); *In re Lupron Sales Practices*, 295 F. Supp. 2d 148, 168 n. 19 (D. Mass. 2003) ("recognition on the part of government regulators of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct").

methodologies on an *ad hoc*, manufacturer, or drug-specific basis. With over 20,000 NDCs in its formulary and over 500 manufacturers represented in Medi-Cal's formulary, Defendants fail to explain why *their* fraudulent inflation of AWPs should have required California to revamp *its* massive payment program or risk foregoing all legal redress focused on Defendants' knowingly fraudulent conduct.[20]

B. Defendants Never Made The Timely, Complete And Full Disclosure Of Their Fraudulently Inflated AWPs That Would Be Required To Mount A Colorable Government Knowledge Defense.

Defendants doggedly misapprehend the degree of full and complete disclosure required to prevail on their government knowledge defense. As this Court has explained, "[e]ven those cases that have found government knowledge to negate the element of falsity have required that the government *possess knowledge of the actual true facts of the claim, not simply knowledge that the claim is generally false*; some have further required that the government actually approve of those true facts." *Mylan Labs.*, 608 F. Supp. 2d at 149 (emphasis added). Defendants would have to show undisputed evidence that not only did they make full and timely disclosure of their fraudulently inflated AWPs, but that the State *formally* and *affirmatively* approved of the alleged wrongful price reporting conduct. No such evidence has been put forth. *See Lachman*, 387 F.3d at 54 ("agency interpretations are only relevant if they are reflected in public

[20] Materials relating to other government efforts to contend with AWP inflation are no more availing to Defendants. For example, in 2000, the Department of Justice and the National Association of Medicaid Fraud Control Units calculated an alternative valuation of certain AWPs, which California ultimately elected not to use. Medi-Cal's decision not to adopt the DOJ AWPs hardly signaled approval of any Defendant's reporting of fraudulently inflated AWPs. Although the DOJ AWPs were the result of a drug pricing investigation, the effort was dropped at the federal level (at the direction of Congress) shortly after it was begun. California did not use the DOJ AWPs because they were determined to be too low and were based on data of uncertain accuracy. Since many of these drugs were administered in doctors' offices, any providers that were inadequately reimbursed would simply stop administering these drugs, causing patients to go to more expensive hospitals for the drugs. (*See* Declaration of Sarah L. Reid in Support of Dey, L.P. and Dey, Inc.'s Motion for Partial Summary Judgment (docket no. 6699), Ex. 43 at CAAG/DHS0076373-75.) Moreover, the DOJ AWPs would have applied to fee-for-service Medi-Cal patients, but not those enrolled in Medi-Cal's extensive managed care programs, and the State's extensive federal and state supplemental rebate program could not function properly if there were two different AWPs used as the cost basis for reimbursement. (*Id.*)

documents . . . . The non-public or informal understandings of agency officials concerning the meaning of a regulation are thus not relevant.").

According to the Second Circuit, "the statutory basis for an FCA claim is the defendant's knowledge of the falsity of its claim, which is not automatically exonerated by any overlapping knowledge [of] government officials." *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1156 (2d Cir.), *cert. denied*, 508 U.S. 973 (1993). Similarly, the Ninth Circuit has stated "[t]hat a defendant *has disclosed all the underlying facts* to the government *may* . . . show that the defendant had no intent to deceive." *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) (emphasis added).[21] The Fourth Circuit has held that the government's knowledge of the facts underlying a false claim negates scienter when the government's "*full knowledge of the material facts* underlying any representations implicit in [defendant's] conduct negates any knowledge that [defendant] had regarding the truth or falsity of those representations." *United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) (emphasis added).

Seemingly oblivious to such precedent, Defendants baldly assert that any disclosure of information to California would have apprised California of the material facts—i.e., the facts and extent of each Defendants' fraudulently inflated AWPs—and is thus sufficient to create a question of fact on the issue of scienter. (Defs. Opp. at 34-36.) But the single case cited by Defendants for this implausible proposition hardly supports Defendants' argument; rather, it reinforces Plaintiffs' position, consistent with other case law. In *United States v. Shasta Services, Inc.*, 440 F. Supp. 2d 1108 (E.D. Cal. 2006), an unsuccessful California Department of

[21] The Ninth Circuit later reinforced this requirement in observing that where the defendant and the government "so completely cooperated and shared all information," claims could not be knowingly false. *United States ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321, 327 (9th Cir. 1995).

Transportation (CalTrans) construction bidder filed a *qui tam* suit against the winning bidder, alleging non-compliance with a bidding requirement. An investigation established that the defendant had complied with all bidding requirements and had, in particular, fully disclosed its compliance efforts immediately after submitting its winning bid, and had later provided additional full disclosure during the investigation. *Id*. at 1110-11. Granting the governments' motions to dismiss, the Court noted "[t]he facts show that there ha[d] been *full disclosure as to the particulars concerning [defendant's] bid both before CalTrans awarded the project in question to [defendant], and before any claim for payment was submitted* by [defendant]." *Id*. at 1113 (emphasis added).

Defendants next observe that an HHS-OIG publication that indicated pharmacies paid, on average, 30 percent below WAC to acquire generic drugs was sufficient to create an issue of fact in Massachusetts' attempt to recover WAC-based Medicaid reimbursement payments, even though the report did not contain defendant- or drug-specific information. Although unclear from their Opposition, Defendants seemingly rely on a single sentence from this Court's Memorandum and Order in the Massachusetts case, *Mylan Labs.*, 608 F. Supp. 2d at 152: "[w]ith respect to the post-2002 period, a Government knowledge defense is viable because the government decided to continue using WAC's as a policy matter." (Defs. Opp. at 35.) That statement, however, is taken out of context and, in isolation, hardly provides Defendants with the type of sweeping protection implied in their Opposition. Defendants claim that California was on notice of the full extent of their fraudulent AWPs by virtue of various government reports.[22] (Defs. Opp. at 34-35.) A complete portrayal of this Court's holding in this respect is instructive:

[22] Defendants also claim that California had "detailed information" due to its alleged receipt of AMPs from Sandoz from 1991 to 1997." (Defs. Opp. at 35-36.) However, according to the Generic Pharmaceutical Association, of which Sandoz and Mylan are members, *AMPs did not provide an accurate reflection of true market prices*. In February 2007 GPhA sent a letter to CMS, stating that AMPs are easily misinterpreted "when payers, state agencies

> Although the Commonwealth came to know that the WACs for generic drugs were false in certain respects beginning in 2001 or 2002, there is scant-to-no evidence that the government earlier *possessed knowledge of the true facts underlying the alleged false claims*. Defendants have presented absolutely no evidence that the government approved them before 2002. Similarly, Defendants have presented no evidence that the Commonwealth *knew that the spreads for drugs were almost frequently greater than 50 percent, consistently in the hundreds, and frequently in the thousands, or that the defendants ever disclosed the actual underlying facts to the government.*

Mylan Labs., 608 F. Supp. 2d at 150 (emphasis added).

Moreover, Defendants' argument runs counter to overwhelming contrary precedent. This is particularly so with respect to Defendants' assertion that "[t]he relevant question is whether California acquiesced in the payment of claims that exceeded providers' actual acquisition costs." (Defs. Opp. at 36.) None of the case law cited by Defendants supports the unsound precept that mere "acquiescence" in fraudulent conduct signals government ratification and approval. Defendants have yet to establish that California ever signaled its approval of the reporting of deliberately inflated AWPs to the State as a basis for Medi-Cal provider reimbursement.

In *United States ex. rel. Englund v. Los Angeles County*, 2006 WL 3097941 (E.D. Cal. Oct. 31, 2006), also relied on by Defendants, the *qui tam* plaintiff alleged that defendant Los Angeles County violated the federal False Claims Act by improperly using state and federal Medicaid funds in the course of providing indigent care under a managed care contract with

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and consumers rely on AMPs to indicate actual prices available in the marketplace." Sandoz agreed with the position taken by GPhA that "AMP is mistakenly perceived as an indicator of market prices, however, it bears little relevance to market price." In 2007, attorneys for GPhA prepared a "white paper" for California, the purposes of which were to explain GPhA's insistence that AMPs were not a reliable basis upon which to calculate pharmacy reimbursement, to talk about the limitations of AMPs, and to express concerns about the confidentiality of AMPs. The white paper conveyed the position of GPhA that using AMPs would not be an accurate way of calculating the price charged by a manufacturer to consumers. It is blatantly disingenuous for Defendants to adhere to GPhA's position regarding the unreliability of AMPs while representing to this Court that AMPs provided California with "knowledge" of market prices. Moreover, the reliability of AMPs is further compromised by the fact that a manufacturer such as Sandoz has the ability to change or restate its AMP data for a period of five calendar quarters following the period it initially provided the data to California. (*See* Plaintiffs' Statement of Additional Undisputed Facts in Opposition to Sandoz Inc.'s Motion for Summary Judgment (docket no. 6787), ¶¶ 4, 12, 13, 15, 18, 21.)

Medi-Cal. Granting the County's motion for summary judgment, the court found it undisputed that the United States knew what the County was doing at all times; that the County had never hidden its actions (a fact which no party disputed); and "that the alleged 'scheme' was well known and public," so as to make it impossible for the County to have had the requisite intent to purposefully defraud the government. *Id*. at *12. As discussed, no such candor occurred here. *Englund* therefore offers no support to Defendants.

Defendants seek further support, again unsuccessfully, from *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931 (10th Cir. 2008), a declined *qui tam* case. In *Orenduff*, the defendant mistakenly relied on the federal government's misclassification of a university as a "minority institution" in response to solicitations from the government for grant proposals from minority institutions. *Id.* at 947. Here, Defendants cannot point to any formal or official pronouncement by any government agency directing (or misdirecting) them to report grossly inflated AWPs. *Orenduff* is thus inapposite to the instant facts.

CONCLUSION

For the reasons set forth above and in Plaintiffs' summary judgment briefs, Plaintiffs respectfully request that the Court deny Defendants' motions for partial summary judgment and grant Plaintiffs' motions for partial summary judgment.

Dated: January 15, 2009

Respectfully submitted,

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VEN-A-CARE OF THE FLORIDA KEYS, INC.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on January 15, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Nicholas N. Paul
NICHOLAS N. PAUL